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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------|---------------------------------|----------------------|---------------------|------------------|
| 10/553,830 | 07/03/2006 | Yoshikazu Morita | 8062-1032 | 6299 |
| 466 YOUNG & TH | 7590 10/15/200 OMPSON | EXAMINER | | |
| 209 Madison St Suite 500 | reet | KIM, TAEYOON | | |
| | ALEXANDRIA, VA 22314 | | | PAPER NUMBER |
| | | | 1651 | |
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| | | | MAIL DATE | DELIVERY MODE |
| | | | 10/15/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | | | |
|--|--|---|--|--|--|--|--|
| Office Action Occurrence | 10/553,830 | MORITA ET AL. | | | | | |
| Office Action Summary | Examiner | Art Unit | | | | | |
| | TAEYOON KIM | 1651 | | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be time will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | lely filed the mailing date of this communication. (35 U.S.C. § 133). | | | | | |
| Status | | | | | | | |
| 1) Responsive to communication(s) filed on | | | | | | | |
| | action is non-final. | | | | | | |
| <i>;</i> — | , | | | | | | |
| | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | | |
| 4)⊠ Claim(s) <u>1-5</u> is/are pending in the application. | | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | | |
| 6) Claim(s) <u>1-5</u> is/are rejected. | · · · · · · · · · · · · · · · · · · · | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | | |
| 8) Claim(s) are subject to restriction and/or | election requirement. | | | | | | |
| Application Papers | · | | | | | | |
| ··· <u> </u> | • | | | | | | |
| 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | | | |
| | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | |
| | | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. | | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| | | | | | | | |
| Attachment(s) | | | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | ite | | | | | | |
| 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 12/18/2007, 10/20/2005. 5) Information Disclosure Statement(s) (PTO/SB/08) 5) Other: | | | | | | | |
| 1 apor 110 (0) minim batto 12/10/2001, 10/20/2000. | | | | | | | |

DETAILED ACTION

Claims 1-5 are pending.

Information Disclosure Statement

The information disclosure statement filed 10/20/2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein, which was crossed out, has not been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Takada et al. (EP 1010430A1; IDS ref.).

Claim 1 is interpreted as a skin collagen production promoter comprising a milkderived basic protein fraction as an active ingredient.

Takada et al. teach a milk-derived basic protein fraction for periodontal application such as mouthwash (cosmetic), food or drink (para. 9) and the fraction contains more than 15% by weight of basic amino acids (para. 9).

Takada et al. also teach a limitation drawn to a process step disclosed in claim 3

to obtain milk-derived basic protein fraction using a cation exchange resin and eluting with a salt concentration of 0.1 to 1 M (para. 11).

Although Takada et al. do not particularly teach that the milk-derived basic protein composition is a skin collagen production promoter, the product of Takada et al. is expected to have the same properties as the claimed invention and thus it is expected that the product of Takada et al. has the same effect on skin collagen production as the claimed invention.

M.P.E.P. § 2111.02 reads, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." As such, the limitation "skin collagen production" does not affect the patentability of the claimed composition. Compositions are defined by their physical, structural, and chemical properties, not by an intended use or application.

M.P.E.P. § 2112.01 recites, "Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present." See *In re Spada* (citations omitted).

M.P.E.P. §2112 also states that "The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's

functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re* Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re* Crish, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel."

Thus, the reference anticipates the claimed subject matter.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Takada et al. (US 5,976,597; IDS ref.).

Takada et al. teach a basic protein and/or a basic peptide composition derived from milk (milk-derived basic protein or peptide) by protease degradation (abstract, col. 1, lines 6-15).

Takada et al. teach the amino acid composition comprising 17.8% of basic amino acid (col. 4, lines 46-47), thus meet the limitation of 15% by weight or more in claim 2.

Takada et al. teach the same process steps of protease degradation (claim 1) and steps of isolating a fraction derived from milk basic protein including an absorption

with a cation exchange resin, and elution with an eluent having a salt concentration of 0.1 to 1 M (col. 2, lines 55-62).

Takada et al. teach that the milk-derived basic protein or basic peptide fraction composition can be taken orally and useful as a supplement to food or drink, therefore, this teaching anticipates the food or beverage product as in claim 4.

Although Takada et al. do not teach that the milk-derived basic protein or basic peptide fraction composition is a skin collagen production promoter or a cosmetic, the product of Takada et al. is expected to have the same properties as the claimed invention and thus the product of Takada et al. is expected to have the same effect on skin collagen production as the claimed invention.

Although Takada et al. do not particularly teach the composition is being used as a cosmetic (intended use) as claimed in claim 5, the purpose of the composition without any distinct physical, chemical and structural properties does not limit the claimed product.

M.P.E.P. § 2111.02 reads, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." As such, the limitation "skin collagen promoter" or "a cosmetic for promoting skin collagen production" does not affect the patentability of the claimed composition. Compositions are defined by their physical, structural, and chemical properties, not by an intended use or application.

M.P.E.P. § 2112.01 recites, "Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present." See *In re Spada* (citations omitted).

M.P.E.P. §2112 also states that "The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re* Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re* Crish, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel."

Thus, the reference anticipates the claimed subject matter.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAEYOON KIM whose telephone number is (571)272-

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9041. The examiner can normally be reached on 8:00 am - 4:00 pm ET (Mon-Thu). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/ Examiner, Art Unit 1651